4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1347]

Michael L. Babich: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Michael L. Babich from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Babich was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Babich was given notice of the proposed permanent debarment and an opportunity to request a hearing to show why he should not be debarred. As of September 2, 2020 (30 days after receipt of the notice), Mr. Babich had not responded. Mr. Babich's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit applications for special termination of debarment to Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, debarments@fda.hhs.gov, or at 240-402-8743.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On January 22, 2020, Mr. Babich was convicted as defined in section 306(l)(1) of the FD&C Act when judgment was entered against him in the U.S. District Court for the District of Massachusetts, after his plea of guilty, to one count of conspiracy in violation of 18 U.S.C. 371 and one count of wire fraud in violation of 18 U.S.C. 1341.

The factual basis for this conviction is as follows: Mr. Babich was the President and Chief Executive Officer of Insys Therapeutics, Inc. (Insys), a Delaware Corporation, with headquarters in Chandler, Arizona. Insys developed and owned a drug called SUBSYS, a liquid formulation of fentanyl to be applied under the tongue. FDA approved SUBSYS for the management of breakthrough pain in adult cancer patients who are already receiving and are already tolerant to opioid therapy for their underlying persistent cancer pain. From May 2012 and continuing until December 2015, Mr. Babich conspired with other employees of Insys to bribe and provide kickbacks, often mailed through the U.S. Postal service, to medical practitioners in various states to get those practitioners to increase prescribing SUBSYS to their patients, many of whom did not have cancer. The bribes and kickbacks took various forms, including honoraria for the practitioners' participation in educational events and payment of the practitioner's staff salaries. To further this conspiracy, Mr. Babich along with his co-conspirators devised a scheme whereby Insys executives conspired to mislead and defraud health insurance providers to ensure those providers approved payment for SUBSYS when it was prescribed for non-cancer patients.

As a result of this conviction FDA sent Mr. Babich, by certified mail on July 16, 2020, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the FD&C Act, that Mr. Babich was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Babich an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Mr. Babich received the proposal on August 3, 2020. Mr. Babich did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Babich has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Babich is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see DATES) (see sections 306(a)(2)(B) and 306(c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mr. Babich, in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Babich provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept

or review any abbreviated new drug application from Mr. Babich during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of section 306 of the FD&C Act, a "drug product" is defined as a drug subject to regulation under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262) (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Any application by Mr. Babich for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2020-N-1347 and sent to the Dockets Management Staff (see ADDRESSES). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at https://www.regulations.gov or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: November 23, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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